Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services and Modify the Policies Governing Them	)	PR Docket 92-235

To: The Commission

COMMENTS OF SPACELABS MEDICAL, INC.

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SUMMARY

SpaceLabs Medical, Inc. ("SpaceLabs"), is a pioneer in the design and manufacture of wireless electrocardiogram ("ECG") telemetry monitors. Its newest generation of monitors (along with those of other manufacturers) operate at extremely low power (e.g., less than 5 mW) on the offset channels in the 450-470 MHz band, and are widely used by hospitals to provide real-time monitoring of ambulatory cardiac patients.

In recent years, as spectrum congestion has increased, it has become exceedingly difficult to ensure the interference-free operation of these wireless ECG monitors, particularly in major urban areas. Thus, SpaceLabs generally supports any effort to reduce spectrum congestion and increase efficiency.

However, the new regulations for the offset channels set out in the Notice of Proposed Rulemaking ("NPRM") are so constraining that there is substantial doubt regarding the ability of future generations of ECG monitors to operate under that regime. As proposed in the NPRM: (1) offset channel bandwidths are far too narrow; (2) adjacent channel power levels are far too high; and (3) the new exclusive-use licensing concept creates financial incentives diametrically opposed to the continued availability of channel capacity for low power medical telemetry.

The wisest long-term solution would be the initiation of a proceeding to allocate new spectrum for the primary use of biomedical telemetry. It is highly likely that new spectrum will become available within the next several years (from the current

federal government pool) that could accommodate the unique needs of the industry. If the Commission were to begin an allocation proceeding now, it could complete that process well in advance of the conclusion of the refarming transition period. This would enable the biomedical telemetry users to amortize existing equipment and avoid the major dislocations that otherwise would be involved in attempting to meet the Part 88 regulatory scheme.

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SpaceLabs Medical, Inc. ("SpaceLabs") hereby submits

initially using technology developed by the company while working with NASA on then-new biomedical telemetry systems for the manned spaceflight program.

SpaceLabs' early generations of ECG monitors (as well as those of other manufacturers) primarily operated in the VHF band, under the provisions of Part 15 of the Rules. See generally SpaceLabs, Inc., 26 F.C.C.2d 40 (1970); Laser Systems and Electronics, Inc., 26 F.C.C.2d 19 (1970). Eventually, the Commission established an exclusive reserve for biomedical telemetry operations under Part 15, on the vacant VHF television channels in the 174-216 MHz band. See 47 C.F.R. § 15.241; Biomedical Telemetry Radio Systems, 33 F.C.C.2d 880 (1972).

However, because of the severe restrictions on power levels inherent in Part 15 operations (which inhibit the [redacted]

impact on the vital medical services presently provided by these telemetry systems.

II. OVERVIEW OF WIRELESS BIOMEDICAL TELEMETRY.

A. System Functions and Capabilities.

An ECG monitoring system records and visually displays the electrical currents that stimulate the contraction of the heart muscle. The system measures that current by means of transducing electrodes attached to the patient's skin at various points on the body. Different electrode placements will generate different "views" of the heart. Irregular heart beats or other cardiac problems are identified by observing distortions in the electrical current represented by the ECG. To ensure accuracy, and to aid in identifying potential cardiac problems before they become acute, it is essential that the telemetry system provide multiple views of the heart. Each view requires a continuous, real-time data stream that must be absolutely error-free. The latest generation of portable ECG monitors, using state-of-the-art digital technology, requires a bandwidth of approximately 12.5 kHz (including guardbands) in order to provide two views of the heart.[1/]

[1/] Portability and cost considerations greatly reduce the flexibility that might otherwise be available to employ bandwidth reduction techniques such as multiple level encoding. The higher power levels required by such techniques mean larger, heavier batteries (or shorter battery life). Increased power also decreases frequency reuse capabilities and, in extreme cases, may pose a threat to patient health and/or to the operation of other electronic equipment frequently encountered in the hospital environment. In general (depending on variables such as building construction and terrain

(continued...)

In any ECG monitoring system, the views of the heart collected by the electrodes must be transmitted to a central collecting point, where the data is converted to a visual image displayed on a monitor screen. In a wireless system, a small, portable unit (weighing approximately 7 oz.) is carried by the patient in a holster-style arrangement. The portable unit collects the data gathered by the electrodes and transmits them to an array of receiving antennas located in the ceiling of the corridors and other common areas of the hospital that are accessible to the patient. The signal is then carried via wire to a central point for processing and viewing, generally at a nurse's station.

Wireless ECG monitors provide both the hospital and the patient with vastly increased flexibility. Except for circumstances in which the patient is nonambulatory (e.g., in intensive care), it is logistically easier, and far more cost-effective, to employ portable units. More importantly, the portable units permit ambulatory patients a great deal of freedom of movement, an aspect of the recovery process that has become increasingly important in the judgment of the medical profession. Shortened patient recovery periods provide substantial medical and financial benefits.

As noted above, biomedical telemetry has fairly rigid operational requirements. Communication must be (1)

[1/](...continued)

instantaneous, (2) continuous, and (3) free from any interference that might cause a data error. The equipment must be sufficiently light in weight as to be easily carried by persons who, by definition, are not in the best physical condition. Because of considerations relating to patient safety and battery life, transmissions must be kept to relatively low powers. Of particular importance in this era of heightened concern over health care costs, the units must be sufficiently robust to withstand constant use without extensive maintenance, yet reasonable in price.

B. Current Frequency Availability.

[redacted]

a secondary basis under Part 90, on certain of the 450-470 MHz splinter channels. See 47 C.F.R. §§ 90.75, 90.217, 90.267.

The existing Part 90 regulatory scheme permits: (1) any type of telemetry operations on most of the 450-470 MHz offset channels; and (2) solely biomedical telemetry in hospitals or similar medical facilities on certain offset channels in the 460 and 465 MHz bands. See 47 C.F.R. §§ 90.75, 90.267. Telemetry devices operating on the offset channels at no more than 20 mW output power are not required to be separately licensed, so long as the hospital or other medical facility in question is licensed by the FCC for other radio operations. See FCC News, Private Radio Action: Commission Eliminates Licensing Requirements for Low-Power Medical Devices in the 450-470 MHz Band, Report No. PR-81, released August 19, 1992. See also Public Notice, Private Radio Bureau Clarifies Licensing Procedures for Certain Low Power Devices, DA 92-665, released June 1, 1992.

The main problem that historically has confronted biomedical telemetry operations in the 450-470 MHz band (as well as in the VHF band under Part 15) is susceptibility to interference, which stems primarily from: (1) telemetry's very low operating power; (2) the limited number of channels available in any given locale, particularly in major urban areas where

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[2/](...continued)
August 14, 1992. Indeed, in those markets in which there is insufficient UHF capacity to meet all HDTV requirements, the Commission has proposed to use the existing VHF TV band, and thus a number of the vacant VHF channels presently available for biomedical telemetry in a given market may be eliminated.

high-power mobile use generally is extensive; and (3) telemetry's secondary status vis-a-vis those high-powered systems. As land mobile uses have increased during the past decade, interference problems have multiplied.

At present, there are approximately 280 splinter channels available for biomedical telemetry. Because telemetry systems must accept interference -- essentially without recourse -- from primary services, many of those 280 channels may be unavailable in a particular locale, depending on the nature of co-channel and adjacent channel operations.[3/] In many major medical centers, upwards of 250 telemetry channels may be in operation at any given time, thereby essentially exhausting the available supply in the 450-470 MHz band. If one or more

C. Next-Generation Telemetry Requirements.

The above-described difficulties are aggravated by the growing demands of the medical profession. First, the use of wireless telemetry is increasing rapidly, particularly given the medical and financial benefits of expedited recovery periods. Wireless ECG monitors make a substantial contribution toward achieving both of those goals, and SpaceLabs' long-term plans envision that within the decade it will not be uncommon for a

increasingly polluted electronic environment, as more and more advanced electronics technology is relied on by the medical profession for diagnostic and treatment purposes, in addition to the increase in the number of personal computers and peripherals used for general administrative tasks.

As is discussed below, the refarmed spectrum to be governed by Part 88 appears to create substantially more splinter channels for biomedical telemetry use. However, this potential increase may prove to be quite illusory, at least as the regulatory scheme presently is proposed.

III. IMPACT OF THE "REFARMING" PROPOSALS.

A. The Proposed Regulatory Structure.

Section 88.1299 of the FCC's proposed rules would, if adopted, provide as follows:

> (a) Low-power mobile stations of 100 mW or less output power may be assigned any frequency separated by 3.125 kHz from a regularly assigned frequency in the 460.646875-460.878125 MHz and 465.646875-465.878125 MHz bands listed in Subpart D, for one-way, non-voice biomedical telemetry operations in hospitals, or in medical or convalescent centers.
>
> (b) Low-power mobile station of [20 mW[5/]] or less output power may be assigned for telemetry operation on any frequency separated by 3.125 kHz from a regularly assigned frequency in the 450-470 MHz bands listed in Subpart D. Licensees need not

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5/ As set out in the NPRM, proposed Section 88.1299(b) establishes a 10 mW limit on output power. However, it is SpaceLabs' understanding, based on informal discussions with the staff of the FCC's Private Radio Bureau ("PRB"), that the reference to 10 mW is a typographical error which will be corrected to 20 mW in the eventual Report and Order.

> obtain a separate authorization for such operation. Such operations will be on a secondary basis.

See NPRM at 278.

It appears from proposed Sections 88.907(a) (NPRM at 238) and 88.1293 (NPRM at 277) that the Commission intends to

[redacted]

3.125 kHz from the main channel, with a bandwidth of 5 kHz. As discussed above, the biomedical telemetry industry is capable of carrying two data streams within an existing offset channel, using recently perfected digital technology to reduce the needed bandwidth (including guardbands) to approximately 12.5 kHz. The increasing demand of the medical profession for additional real-time patient data already is forcing telemetry system manufacturers to be as efficient with their use of spectrum as the state of the technological art will allow, within certain fairly inflexible power, weight and cost constraints.

Indeed, by at least one measure, the biomedical telemetry industry essentially meets the Commission's proposed efficiency requirement already: one telemetry data stream is carried by approximately 6.25 kHz of bandwidth. The problem, as was noted above, is that each telemetry "channel" (i.e., the continuous segment of spectrum authorized to be used by a given transmitter) now must accommodate at least two 6.25 kHz-wide data streams, and within the next decade, that channel must be able to carry up to six patient parameters.[7/]

7/ The existing level of efficiency achieved by the biomedical telemetry industry can be compared to the most advanced narrowband systems presently under

Thus, even if it is assumed that, over the course of the next ten years, the state of the art will advance to the point that the bandwidth needed to carry a present-day two-view telemetry signal could be reduced by a factor of two or three (not necessarily a safe assumption), the bandwidth problem faced by the telemetry industry would not be solved. In essence, a three-fold increase in efficiency would, at best, replicate the status quo, assuming arguendo that the Commission does not reduce the offset channel bandwidth below 12.5 kHz: today, SpaceLabs must fit two 6.25 kHz-wide signals into one channel; tomorrow, it will have to fit six 2 kHz-wide signals into that same space. If the Commission reduced the offset channel bandwidth to 5 kHz, the

bandwidth for a six-parameter telemetry signal. Although such a "channel-hopping" system might be technically feasible, the additional cost of the necessary technology would be prohibitive for biomedical telemetry use.

C. Proposed Offset Channel And Adjacent Channel Power Levels Must Be Reduced.

In order to support the documented needs of the biomedical telemetry industry, the Commission not only must provide for wider bandwidth channels than currently is proposed, it must reduce the power levels permitted on both those channels and on adjacent channels. Under proposed Section 88.429, SpaceLabs has calculated that an adjacent channel operation employing the maximum permitted power must be at least 55 miles away from a standard biomedical telemetry operation in order to avoid interference to the telemetry system.[8/]

However, if the Commission would (1) increase the number of very low power (i.e., 10 mW maximum) offset channels reserved for biomedical telemetry in proposed Section 88.1299(b), and (2) impose a 100 mW limit on all adjacent channels, the separation requirement would be reduced to approximately one mile (depending on antenna height). Even a 1 watt power limit for adjacent channels -- which would result in a separation

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8/ This calculation takes into account certain building penetration losses and other factors relevant to the circumstances involved in biomedical telemetry operations. Of course, even this 55-mile figure may be

requirement of three miles -- would be a significant improvement over the current proposal.

A reduction in power levels for adjacent channels -- with strict restrictions on access to the reserved offset channels -- could provide a much more viable operating environment for biomedical telemetry. However, as noted supra, any such solution also must address the bandwidth problem.

D. The 450-470 MHz Offset Channels And Their Adjacent Main Channels Should Not Be Subject To Acquisition By An Exclusive Use Overlay Licensee.

SpaceLabs applauds the Commission's efforts in the NPRM to devise a regulatory scheme that provides incentives for maximizing the efficiency with which the spectrum is used by various private radio services. The exclusive use overlay ("EUO") licensing concept discussed in the NPRM (at 18-21) holds great potential in this respect. However, SpaceLabs fears that

3. Because telemetry operations generally are restricted to hospitals and other major medical facilities, coordination with telemetry licensees requires that small, randomly situated geographic pockets be accorded substantial protection from

E. An Extended Transition Period Must Be Established For Biomedical Telemetry Operations On The Offset Channels.

As is demonstrated above, the biomedical telemetry industry always has been under intense marketplace pressure to maximize the efficiency with which it uses the spectrum. To date, those incentives have pushed the industry to the point at which two error-free, real-time, continuous data streams can successfully be transmitted by a portable, economically practical processor/transmitter, using approximately 12.5 kHz of bandwidth and less than 5 mW power. The marketplace -- with or without regulatory incentives -- will continue to impose great pressure on the industry to be more efficient.

However, not even the most optimistic technical scenario instills confidence that, in the foreseeable future, the same amount of information as is carried in 12.5 kHz today -- let alone three times as much data -- can successfully be delivered in a commercially viable manner using a 5 kHz channel. Absent an unanticipated technical breakthrough of significant magnitude, the move to 5 kHz offset channels should not occur for at least ten years.

IV. THE COMMISSION SHOULD BEGIN THE PROCESS OF ESTABLISHING A SEPARATE, PRIMARY ALLOCATION FOR BIOMEDICAL TELEMETRY SERVICES.

Several points are clear from the foregoing: (1) biomedical telemetry systems provide an essential medical service, the demand for which will continue to increase for the foreseeable future; (2) the existing allocations are, at best, marginally adequate to maintain the status quo and woefully

inadequate to sustain even modest future growth, let alone the dramatic expansion of biomedical telemetry services anticipated by all informed observers; and (3) it is questionable whether sufficient technical breakthroughs will occur within the next decade to enable biomedical telemetry systems to operate successfully under the regulatory regime proposed in the NPRM.

Put simply, an objective analysis of both the current state of affairs and the reasonably anticipated future leads to the conclusion that the Commission presently should begin the process of establishing a new, primary allocation for very low power biomedical telemetry services. Beginning that process now would enable the Commission to have a new allocation established well before the transition to the 5 kHz-wide offset channels.

As the Commission is aware, Congress is clearly ready -- with strong support from the Executive Branch -- to adopt legislation that will result in the reallocation to the private sector of a substantial amount of spectrum presently assigned to the federal government. It is reasonable to assume that the needs of biomedical telemetry could be met from this pool, particularly if the process of identifying those needs and communicating them to the National Telecommunications and Information Administration were to begin now.

Thus, while SpaceLabs strongly encourages the Commission to modify its refarming proposal to better accommodate the needs of the biomedical telemetry industry within the confines of new Part 88 of the Rules, it must be emphasized that the most rational long-term solution is a separate, primary

allocation. The conjunction of the refarming transition and the federal reallocation presents the Commission with an excellent opportunity to fashion timely and durable relief for this vital industry.

CONCLUSION

[redacted]